REMARKS

Claims 1–28 are pending in the present application. In the Office Action mailed January 14, 2005, the Examiner rejected claim 1 under 35 U.S.C. §112, second paragraph, as being indefinite. The Examiner next rejected claim 28 under 35 U.S.C. §112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements. Claims 1-4, 8-11, 13-19, and 21-27 were rejected under 35 U.S.C. §103(a) as being unpatentable over Rive (USP 6,301,666) in view of Nelson et al. (USP 6,564,104), and further in view of Uchikubo et al. (USP 6,480,762). Claims 5-7 and 12 were rejected under 35 U.S.C. §103(a) as being unpatentable over Rive in view of Nelson et al., and further in view of Uchikubo et al. and Mi et al. (USP 6,523,067). Claim 20 was rejected under 35 U.S.C. §103(a) as being unpatentable over Rive in view of Nelson et al. and further in view of Uchikubo et al. and Lahtinen (WO 99/250086).

Applicant appreciates the withdrawal of the double patenting rejection.

REJECTIONS UNDER §112

The Examiner stated that claim 1 is indefinite under §112, second paragraph, because "[i]t is unclear what qualification for the medical device that Applicant intends to encompass" by calling for "determining...whether the customer is qualified to use the medical device" and "periodically monitoring whether the customer continues to be qualified for the medical device." However, Applicant disagrees because (1) the claim is not indefinite because it need not set forth a preferred embodiment, (2) one of ordinary skill in the art will readily recognize that, within the medical fields, individuals are often required to be qualified to use a given medical device, and (3) the claims are interpreted in light of the Specification, not in a vacuum. That is, individuals not meeting prerequisite educational or training criterion are often precluded from using medical devices. As such, claim 1 calls for a method that includes "determining...whether a set of criteria has been satisfied," wherein one of the "set of criteria" includes whether the customer is qualified to use a particular medical device. As the Examiner has identified, claim 1 does not explicitly call for any specific criterion that may be evaluated to determine whether the customer is qualified, however, one of ordinary skill in the art would be readily apprised of the "set of criteria" necessary to make such a determination. Therefore, claim 1 is not indefinite within the meaning of §112, second paragraph, because (1) it is the Specification that "teaches," not the claims, (2) one of ordinary skill would readily understand and recognize the meaning of that

which is called for in claim 1. see MPEP §2171, and (3) the claims are interpreted in light of the Specification, which clearly sets for a basis for the set of criteria.

Regarding claim 28, the Examiner concluded that the claim was indefinite under the meaning of §112, second paragraph, "for omitting essential structural cooperative relationships between elements." First, as explained below, only the Applicant can identify "essential" elements, not the Examiner. *See* MPEP §2172.01. Manual of Patent Examining Procedure §2172.01 states that "a claim which omits matter ***disclosed*** to be essential to the invention ***as described in the Specification or in other statements of record*** may be rejected...". Further, MPEP §2172.01 is specific that "essential matter" can be identified as such if "***described by the Applicant(s) as necessary to practice the invention***." As such, the Examiner must provide a citation or support within the Specification for the conclusion that any particular element is "essential." However, since *Applicant* has not identified any such elements as essential, the Examiner's rejection must be withdrawn.

Second, when properly interpreted, no "gap between...connections," structural or otherwise, is present. Specifically, since claim 1 calls for "determining whether to grant indefinite use of the option in response to the request based on whether a set of criteria has been satisfied," the Examiner concluded that it is inherently indicated "that the option is not enabled" at the outset and, "therefore, the step of 'disabling the option based on the set of criteria being unsatisfied' [called for in claim 28] could not have occurred." (Emphasis added). However, the Examiner seems to have imputed a time and ordering constraints when interpreting the claims that are not actually present in the claims. That is, while claim 1 and 28 use the qualification status or "unqualification" status to determine whether to enable the option (claim 1) or disable the option (claim 28), there is nothing in the claims that call for these determinations to occur contemporaneously. That is, a customer may be determined to be qualified and have the option enabled, as called for in claim 1. Then, at a later period in time, the customer may be determined to have become unqualified and, as called for in claim 28, the option may then be disabled. In fact, claim 1 explicitly calls for "periodically monitoring whether the customer continues to be qualified for the medical device." As such, claim 28 calls for disabling the option that when it is determined that the customer is no longer "qualified for the medical device." Accordingly, neither claim 1 nor claim 28 is indefinite.

REJECTIONS UNDER §103

The Examiner rejected claims 1-4, 8-11, 13-19, and 21-27 as being unpatentable over Rive in view of Nelson et al. and further in view of Uchikubo et al. Claims 5-7 and 12 were rejected as being unpatentable over Rive in view of Nelson et al., and further in view of Uchikubo et al. and Mi et al. Claim 20 was rejected under 35 U.S.C. §103(a) as being unpatentable over Rive in view of Nelson et al. and further in view of Uchikubo et al. and Lahtinen. Though claims 1, 11, 18, and 22 are independent claims and, thus, require separate and distinct analysis, the Examiner focused the majority of remarks on the elements of claim 1. As such, Applicant's response is similarly focused on claim 1. However, while many of the remarks made with respect to claim 1 are directly applicable to claims 11, 18, and 22, each independent claim requires independent analysis. Therefore, additional remarks in support of the patentability of claims 11, 18, and 22 follow the analysis of claim 1.

CLAIM 1

Regarding claim 1, the Examiner disagreed with Applicant's contention that "Rive fails to teach the activation key is not automatically, self executing or directly enabling the option." Rather, the Examiner stated that "Rive teaches remotely enabling the computer system by use of a password." However, not only is this conclusion contradictory, it is not supported by the art of record.

That is, the Examiner contended that the password of Rive is "automatic" or "self executing." However, one of ordinary skill in the art would readily recognize that a password is neither "automatic" nor "self executing." In fact, if a password was to be "automatic" or "self executing," it would no longer function as a password. That is, by definition, a "password" is "a secret word or phrase that is used to obtain access to a place, information, or a computer system." Cambridge Dictionaries Online (copy enclosed). Should a password be "automatic" or "self executing," one would be enabled to obtain access without being required to "*use*" or proffer the password. Therefore, based on the meaning of the term "password," the password taught by Rive cannot be said to be "automatic" or "self executing."

In this regard, Rive teaches that in response to an activation request, the "support service" utilizes a password that "enables the support service to bypass the restrictions placed on edits to the registry 40 and to disable the restrictions on the registry 40." Col. 15, lns. 45–49. Therefore, Rive is clear that the password is not "automatic" and does not "self execute." Rather, the "support service" uses the password to unlock the registry of a particular computer. Therefore, Rive teaches that enabling user access is not "automatic" or "self executing."

Furthermore, Rive teaches that enabling user access is not responsive to the reception of a password/activation key. That is, Rive is clear that the password is used to "enable[] the support service to bypass the restrictions placed on edits to the registry 40 and to disable the restrictions on the registry 40." Col. 15, lns. 45–49. Therefore, while the local computer includes the inactive application, the password does not serve to actually activate the inactive application, as claimed. This is in direct contrast to claim 1, which calls for "automatically enabling user access to the option resident on the device in response to reception of the activation key." One of ordinary skill will readily recognize that unlocking a previously restricted registry does not include "automatically enabling user access to the option resident on the device in response to reception of the activation key." In fact, Rive expressly reiterates this fact by requiring that once the registry is active (i.e. unlocked by the password), a subsequent and independent step must be taken to actually activate the inactive application. Specifically, Rive teaches that "[h]aving access to the registry 40, the support service may then modify settings to make the desired application available, readily executable, and easily launched in a conventional manner on the computer system 50." Col. 15, lns. 49 53. Rive further defines the step of actually activating the inactive application by stating that "the 'activation' of the desired application involves the (1) restoration of launch icons to the desktop and/or appropriate menus presented by the operating system 62 and (2) the designation of the application as 'allowed application' within the registry 40." Col. 15, lns. 53–57. (Enumeration added). Therefore, Rive does not teach "automatically enabling user access to the option resident on the device in response to reception of the activation key." as called for in claim 1. Rather, Rive teaches that the transmission of the password and the activation are two separate and distinct steps. First, the support service must utilize a password to unlock the registry of the computer system, which was previously protected from being edited. Col. 15, lns. 45–49. Then, only after the registry has been unlocked using the password, Rive teaches the additional and independent step of actually activating the application, which consists of multiple substeps.

The Examiner acknowledged that Rive does not teach or suggest "determining (or authenticating) and monitoring user qualification to use a medical device." Nevertheless, the Examiner summarily concluded that Nelson et al. teaches that which is claimed. To support this conclusion, the Examiner cited column 5, lines 7-18 and column 15, lines 46-67. However, the cited section of column 5 merely states, "Further, it is a typical medical practice to keep an accurate record of past and contemporaneous procedures relating to an IMD uplink with, for example, an IMD programmer, i.e. a computer capable of making changes to the firmware or

software of an IMD." Applicant does not believe that such teaches or suggests the claimed steps of "determining" and "periodically monitoring" whether the customer is and continues to be qualified to use the medical device. Similarly, the cited section of column 15 teaches that "notifications" or "confirmations" may be communicated from a device implanted in a patient to "devices or individuals that have been properly authenticated as having permission to view the patient data." Therefore, Nelson et al. teaches that "patient data" may be communicated from a medical device that has been implanted within a patient to an authenticated person or device. However, this disclosure in no way teaches or suggest the claimed steps of "determining" and "periodically monitoring" whether the customer is and continues to be qualified to use the medical device.

Furthermore, the Examiner acknowledged that neither Rive nor Nelson et al. teach or suggest "remote control activation of a medical device," as called for in claim 1. The Examiner cited yet a third reference for such a teaching. Specifically, the Examiner cited the Abstract of Uchikubo et al. as teaching "remote control activation of a medical device." However, even the Abstract of Uchikubo et al. is clear that the system taught does not include "remote control activation of a medical device." Rather, Uchikubo et al. teaches a system for remotely "rewriting/updating" programs "stored in the storage device" of medical equipment." Abstract of Uchikubo et al. and, *see also*, col. 2, lns. 24-29. This system for software updating (i.e. "rewriting/updating" programs stored on a remote medical device) does not teach or suggest "remote control activation of a medical device," as the Examiner asserted, because updating programs is independent and distinct from permitting/authorizing use.

Additionally, though the Examiner provided a rejection that requires three separate and distinct references to be combined, the Examiner did not provide any support or evidence for the proffered combination other than provide conclusory statements. The burden of establishing a *prima facie* case of obviousness requires the Examiner to affirmatively show that (1) there is a motivation to combine these references in a way done so by the Examiner, other than Applicant's own teaching; (2) the combination would have a reasonable expectation of success; and (3) all the elements of the present claims are present in the references. MPEP §2143. However, the Examiner stated that the proffered combination of Rive and Nelson et al. would be motivated and successful because it would "prevent illegal use of the system and [] provide better patient care." Similarly, the Examiner concluded that the proffered combination of Rive and Uchikubo et al. would be motivated and successful because it would be "cost effective." At best, these conclusions are merely self serving. The Examiner did not supply any evidence to support these

conclusions. For example, how would combining Rive and Uchikubo et al. be cost effective? When prior art references require a selected combination to render obvious a subsequent invention, there must be some reason for the combination other than the hindsight gained from the invention itself, i.e., something in the prior art as a whole must suggest the desirability, and thus the obviousness, of making the combination. *Uniroyal Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 5 U.S.P.Q.2d 1434 (Fed. Cir. 1988). The Examiner must provide that "something in the prior art" to support the proffered combination. Unsupported conclusions are insufficient to meet this burden.

For at least these reasons, claim 1 is patentably distinct from the art of record. Accordingly, claims 2–10 and 28 are also in condition for allowance pursuant to the chain of dependency.

CLAIM 11

With respect to claim 11, the Examiner asserted that "the claim limitation is a system claim that is substantially similar to method claim 1" and is "rejected based on the similar rationale." Applicant does not agree, however, as claim 11 includes numerous elements that differ from claim 1. For example, claim 11 calls for a receiving center to be configured to "enable recurrent use of the at least one inactivated software application resident on the device" "directly responsive to receipt of the access code." (Emphasis added). Nowhere does claim 1 call for any enablement to be "directly responsive to receipt of the access code." For at least this reason, the Examiner has not shown that the art of record teaches or suggests that which is called for in claim 11. In fact, for at least this and the reasons stated with respect to claim 1, Applicant believes claim 11 is patentably distinct from the art of record. Accordingly, claims 12-17 are in condition for allowance pursuant to the chain of dependency.

CLAIM 18

With respect to claim 18, the Examiner again asserted that "the claim limitation is a computer program claim that is substantially similar to method claim 1." As such, the Examiner rejected claim 18 "based on the similar rationale." While the relevant remarks with respect to claim 1 are hereby incorporated, claim 18 is independent and requires review independent from claim 1.

In particular, claim 18 calls for a computer program that causes the computer to perform a multi-tiered validation/qualification check that is not only not taught or suggested by Rive but is inconsistent with the retail sale of personal computer to which Rive is directed. Claim 18 calls for receipt and validation of (1) a user identifier and (2) a system identifier and then, only after

receipt and validation of by the user and system identifier, (3) a determination of user qualification. Accordingly, only after all three criterion have been met, is the computer caused to "generate an electronic enabler", as shown in Fig. 2. On the other hand, Rive does not teach or suggest this multi-tiered and thorough validation/qualification system. Rather, Rive teaches that the only qualification to having an option enabled is compensation. *See* col. 16, lns. 60-67 and col. 17, lns. 7-26. While Rive teaches the use of a system identifier and an option identifier to discern whether the desired option is currently installed on the system, Rive does not consider any user identifier or the qualifications of user.

Furthermore, though the Examiner made no statement of how the art of record applies to this multi-tiered validation/qualification check, neither Nelson et al. and Uchikubo et al. teach or suggest that which is claimed. Rather, Nelson et al. is directed to a system for remotely monitoring medical devices planted within a patient and Uchikubo et al. is directed to a system for remotely rewriting software stored on a medical device. These systems do not include nor do they teach or suggest the claimed multi-tiered validation/qualification check.

Therefore, for at least these reasons, claim 18 is patentably distinct from the art of record. As such, claims 19–21 are in condition for allowance pursuant to the chain of dependency.

CLAIM 22

With respect to claim 22, the Examiner rejected the claim concurrently with claim 1. However, beyond the remarks addressing claim 1, the Examiner asserted that though Rive does not teach or suggest "determine whether the medical imaging device is capable of supporting the option requested," such is "inherent" in the system of Rive.

The Examiner must provide rational or evidence tending to show the asserted inherency. See MPEP §2112. Furthermore, "[t]he fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." In re Rijckaert, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993); In re Oelrich, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). Specifically, in proffering a rejection relying on inherency the Examiner must first overcome a heavy burden. In particular:

> To establish inherency, the extrinsic evidence "must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient."

MPEP §2112, In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950–51 (Fed. Cir. 1999) (citation omitted).

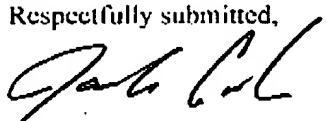
Therefore, "[i]n relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original). It therefore follows that the Examiner must provide objective evidence or cogent technical reasoning to support the conclusion of inherency or the rejection fails and must be withdrawn. Applicant hereby requests such evidence and, if such is provided, requests that any subsequent action be non-final so that Applicant may be afforded the opportunity to respond to any new evidence proffered.

Nevertheless, for at least the reasons previously stated with respect to claims 1, 11, and 18, Applicant believes claim 22 is patentably distinct from the art of record. Furthermore, claims 23-27 are in condition for allowance pursuant to the chain of dependency.

Therefore, in light of at least the foregoing, Applicant respectfully believes that the present application is in condition for allowance. As a result, Applicant respectfully requests timely issuance of a Notice of Allowance for claims 1–28.

Applicant appreciates the Examiner's consideration of these Amendments and Remarks and cordially invites the Examiner to call the undersigned, should the Examiner consider any matters unresolved.

Respectfully submitted,



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